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IN THE

Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Petitioners,

v.

BAYER AG, BAYER CORP., formerly doing business as Miles Inc., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

REPLY BRIEF

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INTRODUCTION

Petitioners alleged below that, absent the $398 million exclusion payments, the patent case would either have: (1) been settled by Bayer granting Barr an early-entry license; or (2) not been settled, and Barr would have won and entered the market. Pet. App. 18a. Under the "patent strength" antitrust standard applied by the Sixth Circuit, D.C. Circuit, and the FTC, evidence that Bayer paid Barr $398 million would have satisfied Petitioners' initial burden under the rule of reason, and, in the Sixth Circuit, would have rendered the exclusion payments per se unlawful. Under the Eleventh Circuit's "patent relitigation" standard, Petitioners could have prevailed by proving that Barr likely would have won the patent case.[1] Under the Second Circuit standard, however, summary judgment was entered against Petitioners because they did not allege that Bayer procured the patent by fraud or that the underlying patent litigation was a sham.

Respondents' argument that there is no split among the circuits relies on tendentious readings of the cases. Their arguments on patent and antitrust law depend on extreme and unsupportable propositions – that "there is no federal 'policy in favor of judicial examination of

1. Bayer misleadingly asserts that Petitioners do not contend that the patent "was invalid." Bayer Br. 22. Petitioners have consistently asserted that, if the patent case had not settled, Barr would have won by proving the patent invalid or unenforceable. Respondents also mislead by asserting that the PTO and the courts subsequently found the patent valid. *Id.* at 6; Barr Br. 3-4. The PTO lacks jurisdiction to decide inequitable conduct defenses, and subsequent challengers did not have time to litigate the fact-intensive defenses that Barr had intended to pursue at trial. *See* Pet. Br. 27; Bayer Supp. App. 11a, 13a-14a. The best defenses to the patent have never been adjudicated.

patent validity'" (Barr Br. 18) and that competitors' joint conduct in excluding competition by private contract should enjoy the same scope of antitrust immunity as a patentee's unilateral conduct in asking government to restrain competition (Bayer Br. 24-26).

I. The Courts Are Divided Over the Proper Standard for Evaluating Whether Exclusion Payments Are Anticompetitive.

Concerning the split between the Second and Eleventh Circuits, the Solicitor General has previously advised this Court that:

> [T]he Eleventh Circuit (unlike the [Second Circuit]) did not purport to hold that proof of "sham" or "objectively baseless" litigation is a prerequisite to antitrust liability.... [or] foreclose the possibility that a party challenging a patent settlement could rely on an ex ante view of the strength of the infringement claim in contending that the settlement was invalid ... [T]herefore, the Eleventh Circuit's standard might permit imposition of antitrust liability in some cases in which the [Second Circuit] standard ... would not.

United States Amicus Curiae Br., *Joblove v. Barr Labs., Inc.*, *No.* 06-830 ["*Tamoxifen Br.*"] at 16 (S. Ct. May 2007).[2]

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2. The Solicitor General urged the Court to deny certiorari in *Tamoxifen* because the claims there "appear[ed] to be moot," *Tamoxifen Br.* at 17, as were the claims of the plaintiffs in the Federal Circuit's *Ciprofloxacin* case, Pet. Br. 33.

The circuit split prevents practitioners from giving clients reliable advice. *See, e.g.*, I Herbert Hovenkamp, et al., IP AND ANTITRUST: *An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 15.3, at 15-29 (2d ed. 2010 Supp.) ["Hovenkamp, IP AND ANTITRUST"] (noting the circuits' "widely different outcomes, ranging from per se illegality to per se legality and including various sorts of rule of reason analysis in between"); Br. Amici Curiae of the States of California, et al., at 3 ("The Attorneys General need guidance as to the legality of reverse payment agreements")[3]; Br. Amici Curiae of 86... Professors, at 6 (three-way split precludes reliable advice). The Solicitor General previously identified *this case* as a possible vehicle for the Court to resolve the exclusion payment issue. United States Amicus Curiae Br., *Federal Trade Comm'n v. Schering-Plough Corp.*, No. 05-273 at 1, 20 (S. Ct. May 2006).

Respondents erroneously deny that there is any circuit split:

Sixth Circuit/D.C. Circuit/FTC. Relying on a single footnote, Respondents assert that the Sixth Circuit condemned the agreement in *Cardizem* because one clause would have precluded the generic from entering even with a hypothetical, concededly non-infringing product. Bayer Br. 15; Barr Br. 12. The Sixth Circuit's analysis, however, hinged on the real competitive effects of blocking entry of a real product whose infringement was contested in the patent litigation, not the hypothetical effects of blocking a hypothetical product. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 902, 907-08 (6th Cir. 2003).

3. Unless otherwise noted, citations to amicus briefs are to those filed with the Court in this case.

The D.C. Circuit applied the patent strength standard to the same agreement without even pausing to refer to the hypothetical-product clause on which Respondents rely. *Andrx Pharm. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809, 813 (D.C. Cir. 2001). The FTC also applies the patent strength standard without regard to the presence or absence of such a clause.

Just as tellingly, other courts have refused to apply the patent strength standard despite the presence of hypothetical-product clauses at least as broad as the one in *Cardizem*: the Eleventh Circuit rejected *Cardizem* and applied a patent relitigation standard, *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003), and a Third Circuit district court rejected *Cardizem* and adopted the Second Circuit standard, *In re K-Dur Antitrust Litig.*, No. 01-1652, 2009 WL 508869, at *28 (D.N.J. Feb. 6, 2009).[4] Respondents cannot distinguish *Cardizem* based on a distinction that is honored by neither the courts that apply the patent strength standard nor those that reject it.

Eleventh Circuit. The Eleventh Circuit in *Valley Drug* directed the district court on remand to determine the "scope of the exclusionary potential of the patent" by comparing the agreement to "the protections afforded

4. The clause in *Cardizem* precluded entry of the challenged generic product "or other bioequivalent or generic version of Cardizem CD," *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, 696 (E.D. Mich. 2000); the *Valley Drug* clause precluded entry of the challenged generic product or "any pharmaceutical product containing any form of terazosin hydrochloride," 344 F.3d at 1300; and the *K-Dur* clause precluded entry of the challenged generic product or "any potassium chloride product," 2009 WL 508869, at *10.

by the preliminary injunction and stay mechanisms and considered in light of the likelihood of [the brand's] obtaining such protections." 344 F.3d at 1312. Because the court used the "exclusionary scope" language later used by the Second Circuit, Respondents assert that the Eleventh Circuit must have meant to adopt the fraud/sham standard rather than the patent relitigation standard. *See* Bayer Br. 18; Barr Br. 16.

On remand in *Valley Drug*, however, the district court unambiguously applied the patent relitigation standard, focusing on "the likely outcomes of the patent litigation that was pending at the time the parties entered into the Agreement.... By exploring the likely outcomes of the litigation, the Court can delineate the protections afforded by the patent...." *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1299 (S.D. Fla. 2005). Expressly holding that Abbott's infringement claim was not a sham, the court nevertheless held the exclusion payments unlawful because the patent claim "was weak and unlikely to result in a District Court finding that the '207 patent was valid, [and] it follows that Abbott was unlikely to obtain a preliminary injunction to keep Geneva off the market through appellate resolution...." *Id.* at 1306.

The Eleventh Circuit standard is read the same way by the United States, *see supra* at 2, by other courts, *e.g.*, *King Drug Co. v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 534 (E.D. Pa. 2010) (relying on *Valley Drug*, finding invalidity and non-infringement allegations sufficient to show exclusion payments "exceeded the exclusionary power of [a] patent because similar protection could not have been obtained by enforcing the patent through litigation"), and by leading commentators, *e.g.*, Hovenkamp, IP AND

ANTITRUST, at 15-36 (under *Valley Drug* "the legality of the settlement agreement depend[s] on whether the patentee would in fact have won the underlying patent suit").

Respondents assert that all of these authorities are wrong, pointing to *Valley Drug*'s statement that plaintiffs cannot impose antitrust liability "merely because the patent is subsequently declared invalid." *See* 344 F.3d at 1308; Bayer Br. 18. In the underlying patent litigation, the patent was ultimately found invalid, and this language noted only that such a subsequent finding cannot justify antitrust liability because an agreement must be judged as of the time it was made; the district court was to determine the likelihood of a preliminary injunction without the benefit of hindsight. 344 F.3d at 1306. *See also In re Terazosin*, 352 F. Supp. 2d at 1302; Hovenkamp, IP AND ANTITRUST, at 15-35.

II. The Second Circuit's Standard Conflicts with This Court's Precedents.

Patent Cases. Respondents assert that, absent fraud or sham litigation, this Court's patent cases permit litigants to settle "on whatever terms they see fit" as long as the exclusion does not exceed the patent's temporal or subject matter scope. Barr Br. 18; Bayer Br. 23-24. Thus, a patentee with only a colorable claim -- say, only a 20% chance of winning -- can pay the alleged infringer (including an amount greater than he could have made by winning the patent case) to confess validity and infringement and stay out of the market until the patent expires.

Spanning two administrations, however, the United States has made clear that the Second Circuit's standard is

"insufficiently stringent" and "erroneous." *Tamoxifen Br.* at 8, 16. Courts should "at a minimum ... take into account the relative likelihood of success of the parties' claims, viewed ex ante." *Id.* at 12. The circuit's standard "offers no protection to the public interest in eliminating undeserved patents." United States Br., *In re Ciprofloxacin*, No. 05-2852 at 15 (2d Cir. July 6, 2009). The standard "is without justification in competition or innovation policy" and "improperly undermines the balance Congress struck in the Patent Act between the public interest in encouraging innovation and the public interest in competition." United States Br. Amicus Curiae, *In re Ciprofloxacin*, No. 05-2852 at 5, 3 (2d Cir. June 3, 2010); *see also* Br. Amicus Curiae of American Antitrust Institute, at 14 (standard "confuse[s] the right of a patentee to exclude others ... with a supposed right to pay potential competitors not to test the validity of a patent").

This Court in *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 344 (1971), made clear that the public interest in patents gives rise to two lines of cases -- one requiring that exclusion not exceed the patent's subject matter and temporal scope, and another "encourag[ing] authoritative testing of patent validity." *See also* Br. Amici Curiae of Consumer Fed. of America, et al., at 23 ("if the patent is not valid, it does not have any scope"); Hovenkamp, IP AND ANTITRUST, at 15-49 ("The legitimate exclusion value of a pharmaceutical patent is the power it actually confers over competition, which is in turn a function of the scope of the patent and its chance of being held valid."). Respondents' opposition is founded on the contention that this second line of authority does not exist, that "there is no federal 'policy in favor of judicial examination of patent validity.'" Barr Br. 18.

Respondents are wrong. See the cases cited in Petitioners' Brief at 24-26, more cases cited in *Blonder-Tongue Labs.*, 402 U.S. at 344-45, and yet more cases cited in *United States v. Glaxo Group Ltd.*, 410 U.S. 52, 57 (1973). Indeed, recently the generic manufacturers successfully urged this Court to decide whether the "clear and convincing evidence" standard applies to the defense of patent invalidity. Br. Amici Curiae of Teva Pharmaceuticals USA, Inc., et al., *Microsoft Corp. v. i4i L.P.*, No. 10-290 (S. Ct. Sept. 29, 2010), *cert. granted* (Nov. 29, 2010). The generics' trade association correctly asserted that "the public have a vital interest" in "having ... invalidity challenges fairly and realistically assessed under appropriate standards," thus "ensuring that invalid patents are not used to stifle legitimate innovation and new products." *Id.* at 4. This vital public interest in fair and realistic invalidity challenges is not served when generics share patentees' monopoly profits in exchange for forgoing those challenges and staying out of the market.

Nor do Respondents deny that the Second Circuit standard conflicts with the Hatch-Waxman Act's incentives for generics to enter the market through patent litigation and the Act's denial of automatic exclusion of generics after 30 months. *See* Pet. Br. 29-30; *see also* Br. Amicus Curiae of AARP, at 11 (if Second Circuit standard prevails, "the patent-challenge provisions of the Hatch-Waxman Act would be eviscerated, and American consumers would be left to pay the price"). Respondents instead assert that the Act alters the traditional risks incurred by infringers in patent litigation, and that these altered risks make a patentee's payments to the alleged infringer a "natural by-product" of the Act. Bayer Br. 23. Both parts of Respondents' argument are wrong. The

Act does not redistribute the traditional patent-litigation risks, because the patentee can choose to either invoke the automatic 30-month stay or decline it and assert a traditional patent claim for damages. *See* Pet. Br. 28 n.10. Even when the patentee chooses the 30-month stay rather than the damage claim and its resulting settlement leverage, nothing in the Act justifies a payment from the patentee to the generic. Litigants can -- and, before the *Tamoxifen* decision, did -- routinely settle Hatch-Waxman cases with early-entry licenses rather than exclusion payments. *See* Pet. App. 33a. The Act intentionally increased the incentives for generic entry. Pet. Br. 28. When Respondents reacted to the statutory opening of the market by agreeing not to compete, the courts should have subjected that conduct to intense antitrust scrutiny, not excused it as "natural."

Antitrust Law. Respondents concede that the Second Circuit standard is built on *Walker Process Equip., Inc. v. Ford Mach. & Chem. Corp.*, 382 U.S. 172 (1965). Bayer Br. 24-25; Barr Br. 21. Petitioners demonstrated at length that *Walker Process* provides antitrust immunity only for a patentee's unilateral conduct in asking the government to restrain competition. Pet. Br. 31-33. The United States agrees: "The court of appeals primarily erred by focusing on whether the underlying patent infringement claim was 'objectively baseless' – a standard typically used in determining whether a defendant is entitled to antitrust immunity under the *Noerr-Pennington* doctrine." *Tamoxifen Br.* at 13. Respondents have no answer, offering a mere assertion that *Walker Process* somehow immunizes "parties" who jointly restrain competition through private agreement. Bayer Br. 25.

Lastly, Respondents' antitrust analysis hinges on their insistence that there is no competitive difference between exclusion payment settlements and licensed entry settlements. *Id.* at 26; Barr Br. 18. Petitioners demonstrated, however, that exclusion payment settlements result in exclusion rather than entry; are determined by the sharing of monopoly profits rather than the patent's strength; sever the connection between the generic's interests and those of consumers; and deliver no benefits to consumers. Licensed entry settlements, in contrast, result in entry of the generic; are determined solely by the patent's strength; preserve the connection between the generic entrant's interests and those of consumers; and deliver to consumers the risk-adjusted benefits of the patent litigation. *See* Pet. Br. 10; *see also* Hovenkamp, IP AND ANTITRUST, at 15-49.

III. This Case Is the Right Vehicle to Resolve This Recurring Issue of Enormous Public Importance.

Respondents do not deny that this case is the Court's last chance to decide the exclusion payment issue without potentially having first to determine whether a complex business arrangement between the brand and generic constitutes a payment. *See* Pet. Br. 34-35; Hovenkamp, IP AND ANTITRUST, at 15-40 (noting "the increasing tendency of settling parties to complicate their settlements to dissuade antitrust scrutiny"). Respondents nevertheless assert that certiorari is inadvisable because this case arose before 2003, when Congress amended the statutory scheme to prevent the brand's settlement with the first-filing generic from raising a statutory bar to entry by later generics. *See* Bayer Br. 33. Respondents concede, however, that the Second Circuit held that the settlement

agreement in this case, despite arising before 2003, did not in fact raise such a statutory bar. *Id.* at 32.[5] So there is no distinction on this issue between this case and those arising after 2003.

Nor do Respondents deny that in 2003 Congress required exclusion payment agreements to be filed with the DOJ and FTC so that they would be prosecuted, or that Respondents' industry representatives had testified that this would solve the exclusion-payment problem because these agreements are unlawful under the Sherman Act. *See* Pet. Br. 4. Respondents now suggest that the Court should stay its hand and require that Congress specifically legislate against exclusion payments yet again. Bayer Br. 34; Barr Br. 22. But the proper interpretation of the Sherman Act is the responsibility of this Court, not Congress. *See State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997) (courts have a clear mandate to shape rules that protect consumers); *see also Monell v. Dep't of Social Services*, 436 U.S. 658, 695 (1978) (Court should not "place on the shoulders of Congress the burden of the Court's own error"). Indeed, PhRMA and its allies are successfully forestalling further Congressional action by making this very point. *See, e.g., The Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706, Before H. Comm. on Energy and Commerce*, 111th Cong. (Mar. 31, 2009) (statement of PhRMA General Counsel, at 16) (arguing that courts, not Congress, should decide whether exclusion payments are anticompetitive).

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5. The *legal bottleneck* issue is different from the *practical* delay that occurs -- both before and after 2003 -- as a result of a settlement with the first-filing generic (and that in fact occurred in this case). *See* Pet. Br. 26; Bayer Supp. App. 12a.

CONCLUSION

The petition should be granted.

Respectfully submitted,

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